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Media Release







Roche receives FDA clearance for the Cobas AmpliScreen System

Significantly strengthens Roche's position in the blood screening business

The U.S. Food and Drug Administration (FDA) has granted clearance of Roche's Cobas AmpliScreen System. The Cobas AmpliScreen System is intended for use in laboratories testing human plasma specimens, for example to detect Hepatitis C (HCV) and Human Immunodeficiency Virus (HIV-1) viruses. The System automates the sample dilution and pooling procedures as well as the amplification and detection steps for analysis of specimens using the Polymerase Chain Reaction (PCR)-based nucleic acid amplification methods.

"This is a significant milestone for our company's PCR blood screening business," stated Heino von Prondzynski, Head of Roche Diagnostics and a member of Roche's Corporate Executive Committee. "It's extremely rewarding to see the technical, financial and human resources that we have invested for several years in this important market sector being recognized. This will hepping customers to offer safer blood screening."

Roche also expects to receive FDA approval of the two PCR-based nucleic acid based technologTHOMSON (NAT) tests for HCV and HIV-1, which are to be used with the Cobas AmpliScreen System. RoEMANCIAL AmpliScreen blood screening tests for HCV and HIV-1, are already approved for commercial use in Italy, France, Germany, Australia and Switzerland. Ruche screens 100 percent of the blood supply in Japan (through its work with the Japanese Red Cross), the Netherlands and the United Kingdom, as well as more than 75 percent of Italy and France's blood donations. The products are also used in other countries where registration is not required. Sales for Roche's blood screening business are on target at 150 million Swiss France during 2002.

The Cobas AmpliScreen System, along with Roche's Cobas AmpliScreen HCV Test, and the Cobas AmpliScreen HIV-1 Test, have been used by America's Blood Centers since 1999 under Investigational New Drug Applications (INDs) to screen blood donations for the presence of the

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HCV and HIV-1 RNA viruses. This network of local, non-profit, community blood centers collects nearly half of the U.S. blood supply and a quarter of the Canadian blood supply.

"We've really seen the difference that NAT testing can make in reducing the window period, or number of days, between the time that a person contracts HIV or HCV and when the viruses can be detected using current FDA-approved serological tests," says Celso Bianco MD, Executive Vice President of America's Blood Centers and an expert on medical issues within the blood banking community. "Roche is to be commended for their ongoing commitment to automating NAT testing as it truly helps improve blood safety," he continued.

About the COBAS AmpliScreen System

The Cobas AmpliScreen System combines a commercially available pipetting/diluting instrument and an automated bench top analyzer (Roche's Cobas Amplicor Analyzer) to automate the sample preparation pooling amplification and detection steps of the Polymerase Chain Reaction (PCR) process. PCR allows scientists to copy a single segment of DNA billions of times, making it possible to take a specimen, such as a bacteria or virus containing genetic material weighing only one trillionth of a gram, and copy its genetic sequence over and over. Within hours, a test sample sufficient to confirm the presence or absence of a virus or bacteria is generated.

The Cobas AmpliScreen System is designed for use with the Cobas AmpliScreen HCV Test, version 2.0 and the Cobas AmpliScreen HIV-1 Test, version 1.5. Both tests are qualitative in vitro tests for the direct detection of Hepatitis C Virus RNA and Human Immunodeficiency Virus (HIV-1) RNA in human plasma. Roche filed a Biological License Application with the FDA for these two tests earlier this year.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups. The company's two core businesses in pharmaceuticals and diagnostics provide innovative products and services that address prevention, diagnosis and treatment of diseases, thus enhancing people's health and quality of life. The two core businesses achieved a turnover of 13.1 hillion Swiss Francs in the 1" half of 2002 and employed about 57,000 employees worldwide. Roche's Diagnostics Division, the world leader in in vitro diagnostics with a uniquely broad product portfolio, supplies a wide array of innovative testing products and services used by researchers, physicians, patients, hospitals and laboratories worldwide. For further information, please visit Roche's website at www.roche.com

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Media Release



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Basel, December 04, 2002

Pegasys in combination with Copegus approved in the US for the treatment of Hepatitis C

Basel, Switzerland — Roche announced today that the U.S. Food and Drug Administration (FDA) has approved combination therapy with Pegasys (peginterferon alfa-2a) and Copegus (Roche's ribavirin) for the treatment of hepatitis C.

Pegasys and Copegus combination therapy was granted a priority review designation by the FDA and received a unanimous recommendation for approval by the FDA's Antiviral Drugs Advisory Committee on November 14th. Pegasys, peginterferon alfa-2a, alone or in combination with Copegus, is indicated for the treatment of adults with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon alfa. Patients in whom efficacy was demonstrated included patients with compensated liver disease and histological evidence of cirrhosis (Child-Pugh class A). Pegasys was already approved as monotherapy for the treatment of adults with chronic hepatitis C on October 16, 2002.

"We are pleased to have a Package Insert that reflects the efficacy data seen in our two pivotal combination studies," said William Burns, head of the pharmaceutical division at Roche. "These studies demonstrated that Pegasys combination therapy has consistently higher response rates compared to conventional interferon therapy regardless of whether a patient is infected with a more resistant virus, like genotype 1, or has other complicating factors such as more advanced liver disease."

For less treatment resistant genotype 2 and 3 disease, the Pegasys combination marks the first time that a pegylated interferon will be indicated for 24 weeks of therapy (current conventional treatment is up to one year) as well as having a tailored ribavirin dose to improve tolerability.

Pegasys and Copegus combination therapy was granted approval based on the results of two pivotal Phase III clinical trials that demonstrate it is an effective treatment for patients with chronic hepatitis C.

The pivotal study completed most recently evaluated the effects of the duration (24 weeks compared to 48 weeks) of Pegasys (180mcg once weeldy) and Copegus treatment, and the daily dose of Copegus (800mg compared to 1000 for patients weighing less than 75 kg and 1200 for patients equal to or more than 75 kg) in patients with chronic hepaticis.

The study showed that genotype 2 and 3 patients achieved similar sustained virological response rates when treated with a 24-week regimen of Pegasys and 800mg Copegus compared to a 48 week regimen of Pegasys and 1000-1200mg Copegus, and therefore only require 24 weeks of treatment. Genotype 2 and 3 patients who were treated with the 24 week lower Copegus dose regimen experienced fewer side effects. Sustained virological response refers to a patient's continued undetectable serum hepatitis C RNA levels 24 weeks after finishing a course of treatment.

Genotype I patients who were treated with the a 48-week regimen of Pegasys and 1000-1200 mg Copegus had higher sustained virological response rates compared to those treated with the 24 week lower Copegus dose regimen.

Sustained virological response rates for these groups treated with Pegasys combination therapy were:

- Genotype 1: 48 weeks duration with 1000 1200mg Copegus: 51%SVR this is the most prevalent genotype in the United States, accounting for approximately 74% of the HCV-infected population.
- Genotype 2: 24 weeks duration with 800mg Copegus: 90% SVR
- Genotype 3: 24 weeks duration with 800mg Copegus: 77% SVR

The other pivotal study was published in the September 26, 2002 New England Journal of Medicine and showed that Pegasys and Copegus combination therapy is a more effective treatment for chronic hepatitis C than interferon alfa-2b and ribavirin. The sustained virological response rate in the Pegasys and Copegus treated patients was 53% compared to 44% in the interferon alfa-2b and

ribavirin group.

In both studies, virus genotype was clearly the strongest predictor of whether or not a patient achieved a sustained virological response. Both trials also showed that physicians can determine within 12 – 24 weeks if a patient is unlikely to attain a sustained virological response with Pegasys and Copegus.

About Pegasys and Copegus

Pegasys is available as a ready-to-administer solution. Each weekly subcutaneous injection contains 180mcg of pegylated interferon alfa-2a, which is the recommended dose for all patients, regardless of body weight. Copegus, available as a 200 mg tablet, is administered at 800 - 1200 mg taken twice daily as a split dose. The recommended dose of Copegus and duration for Pegasys/Copegus therapy is based on viral genotype. The two products will be sold separately.

To date, more than 50 countries have approved Pegasys, and Copegus was recently approved by all European Union member states, paving the way for local country approvals during the next few months. Pegasys has already gained significant market shares in countries like Brazil, Mexico, Germany, Switzerland and the UK where it was launched during the last few months.

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Roche is committed to the viral hepatitis disease area, having introduced Roferon-A for hepatitis C, followed by Pegasys in hepatitis C, with studies currently being conducted on its efficacy in hepatitis B. Roche also manufactures the COBAS AMPLICOR® HCV Test, v2.0 and the AMPLICOR HCV MONITOR™ Test, v2.0 - two tests used to detect the presence of, and quantify, HCV RNA in a person's blood. Roche's commitment to hepatitis has been further reinforced by the in-licensing of levovirin, an alternative antiviral. Levovirin will be studied with the objective of demonstrating superior tolerability over the current standard, ribavirin.

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Investor Update

December 3, 2002

Roche files marketing applications for Valcyte® in solid organ transplantation

Simpler dosing regimen for anti-CMV treatment set to provide major benefit over current therapy for solid organ transplant recipients

Roche announced today that regulatory approval applications for its new cytomegalovirus (CMV) drug Valcyte (valganciclovir), have been filed in the USA, the European Union and Switzerland for use in solid organ transplant recipients. The applications are based on data from clinical studies which show that Valcyte is as safe and efficacious as the current gold standard therapy, Cymevene (ganciclovir). In addition, Valcyte has the added advantage of a simpler patient-friendly dosing regimen patients need only take two tablets of Valcyte once a day compared with 4 capsules of Cymevene three times a day.

"CMV is an infection that, without prophylaxis, occurs in a large majority of solid organ transplant recipients, causing infectious diseases such as pneumonia and hepatitis, and can also cause acute and chronic injury of the grafted organ," comments Dr Mark Pescovitz, Professor of Surgery and Microbiology and Immunology, and Director of Transplant Surgery at Indiana University. "Valcyte, with its excellent bioavailability and the ability to administer the drug safely for prolonged periods, is a significant advance for CMV prophylaxis,"

"For many years, Roche has remained a global leader in post-transplantation immunosuppression. The regulatory filings for Valcyte represent an important milestone in our continued commitment to this category, which we hope will enable us to bring added benefits to patients around the world," said Hari Kumar, Global Leader Valcyte, Roche. "The simpler dosing regimen of Valcyte is yet a further improvement for patients in whom compliance can be an issue."

About Valcyte

Valcyte, a prodrug of Roche's existing anti-CMV treatment, Cymevene, was developed in response to the need for more convenient and patient-friendly administration of ganciclovir. Cymevene is the number one treatment of choice for CMV disease worldwide.

About Roche

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